REMARKS/ARGUMENTS

Claims 32, 33, 36, 37 and 40-47 are now pending in this application.

Claims 1-31 were previously canceled. In this amendment claims 34, 35, 38, 39 and 48-63 have been canceled.

Claims 32 and 37 are the only remaining independent claims and have been amended here.

The amendments to independent claim 32 are fully supported within the originally filed application and for convenience applicants point out that support for these amendments can be found within previously pending now canceled claims 34, 35, 38 and 39.

The amendments to claim 37 are supported within the originally filed application and for convenience applicants point out that these amendments are supported within previously pending now canceled claims 38 and 39.

No new matter has been added.

Rejection under 35 U.S.C. §103

Previous claims 32-63 were rejected under 35 U.S.C. §103 as unpatentable over U.S. Patent 4,388,574 to Ingebrethsen. The rejection is traversed as applied and as it might be applied to the presently pending claims.

The Examiner has correctly pointed out that Ingebrethsen discloses and aerosol drug delivery device which includes the heating element 72 shown in Figure 1. The heating element can be in thermal contact with a conducting agent 77 also shown in Figure 1. Further, the Examiner has correctly recognized that Ingebrethsen does not disclose the particular heating element materials, wire gauge sizes, weights or other parameters of the heating elements disclosed and claimed by applicants.

The rejection suggests that the particular parameters of the heating element disclosed and claimed by applicants would be obvious to one of ordinary skill in the art. It is applicants' position that the particular combination of characteristics are not obvious from Ingebrethsen. Further, it is applicants' position that the particular combination of parameters claimed with respect to applicants heating element provides improved unexpected results in connection with both a method for creating an aerosol as claimed within independent claim 32 and a device as claimed within independent claim 37.

Applicants recognize that Ingebrethsen does mention the possibility of using a battery as a power source. However, there is no teaching with respect to how this could be achieved. The heating element must meet very precise specifications in order to be useful in aerosolized drug delivery. It must be

possible for the heating element to have a sufficient heat capacity such that the heating element can hold the required amount of energy necessary to heat the aerosol. Further, the heating element must have sufficient surface area such that the energy stored in the heating element can be quickly and efficiently given back to the aerosol in order to have the desired result of evaporating away excipient material to create smaller particles for inhalation.

In addition to these requirements the heating element must be one that is capable of being heated by the use of a relatively small energy source such as a battery as claimed by applicants. The heating element and battery must be light weight so that the device can be easily carried and used.

When one skilled in the art considers the infinite number of possibilities for changing the composition of the metal or other material used, the shape of the heating element such as in the form of a wire and the large number of different possible wire gauges as well as the heating capacity, surface area and total weight of the heating element the correct precise specifications to obtain the desired results are far from obvious.

The cited art does not discuss wire gauge and wire gauge has properties which are essential for consideration in obtaining the desired results. By changing the wire gauge one can change the heat capacity of the heating element as well as the surface area. Both of these parameters must be taken into consideration to obtain the desired results and obtain the proper heat capacity and thus the preheat time as well as the cool-down time where the energy is given back to the aerosol. Those skilled in the art will recognize that the same heat capacity obtained with a long thin wire could also be achieved with a short thick wire. However, the heat transfer properties of the thin and the thick wire are completely different due to the difference surface areas. In that the cited are does not discuss wire gauge it is not seen how using a particular wire gauge would be obvious based on the cited art.

Different types of metal will have different total heat capacities and producing a wire of a particular gauge comprised of a particular material having a particular total heat capacity is important to obtain the desired results. However, extremely expensive or heavy metals cannot be used. The heating element must be designed such that when used in a drug delivery device the heat present in the heating device can be given back to the aerosol in a very short period of time during the cycle of the patient's inhalation. Although applicants' heating element takes into consideration all of these different parameters to obtain the desired results the Ingebrethsen reference does not discuss these parameters or how to obtain the desired result.

Conclusion

Although the claims have been rejected as obvious over Ingebrethsen the Examiner has correctly recognized that the art does not disclose the particular parameters claimed with respect to applicants' heating element. There are an infinite number of different possibilities for creating a heating element and the cited art does not teach how to adjust those parameters in order to obtain the desired results of a small light-weight heating element which can be readily heated by a small battery and at the same time give up energy to the aerosol in order to drive off excipient material to create smaller particles – and do such in a short period of time and during a patient's inhalation. Absent applicants' teachings the world has not been taught how to produce a hand-held portable inhalation device with a heating element that is useful in terms of enhancing aerosolized drug delivery. In view of such reconsideration and withdrawal of the rejection is respectfully requested.

In the event petitions are required or fees are due applicants petition for any required relief and authorize the Commissioner to charge the costs of such petitions or other required fees to Deposit Account No. 50-0815, order number AERX-062CON3.

Respectfully submitted,
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